COMMENTS AND RESPONSES

Comparison of Negative Pressure Wound Therapy Using Vacuum-Assisted Closure With Advanced Moist Wound Therapy in the Treatment of Diabetic Foot Ulcers: a Multicenter Randomized Controlled Trial

Response to Hemkens and Waltering

We appreciate Dr. Hemkens and Dr. Waltering's (1) comments on our recently published article on the use of negative pressure wound therapy (NPWT) as delivered by vacuum-assisted closure therapy in the treatment of diabetic foot ulcers (2).

We thank Hemkens and Waltering for recognizing the difficulty in conducting this randomized clinical trial in a blinded fashion. However, we did insure that therapy selection was conducted in a blinded fashion. Neither the physician nor the patient was aware of the treatment assignment before enrolling. Hemkins and Waltering also state that there was a high proportion of censored subject data (33%, $n = 11$). Given age, health status, and duration of treatment, the finding that one-third were censored does not seem surprising or unusual.

Hemkens and Waltering question the criteria for discontinuation and comment that comparability in censoring over time cannot be assessed because data on the number of subjects at risk are not presented in Fig. 2. For both NPWT and advanced moist wound therapy (AMWT), the reasons shown for subjects lost to follow-up and discontinued were clearly and explicitly stated in Fig. 1. Although greater details in the RESULTS section would have been useful, the journal's word count limitations precluded elaboration of these specific findings. Data on the number of subjects at risk were not calculated for Fig. 2.

As for interpretation of the Kaplan-Meier analysis of "time to complete ulcer closure (Fig. 2)," Hemkens and Waltering have calculated the values to be 58% (NPWT) and 38% (AMWT) based on probability of ulcer closure. However, the data reported (43.2%, NPWT; 28.9%, AMWT; $P = 0.007$) were based on proportions of the number of actual closures compared with total patients from each treatment arm. Intent-to-treat analysis is a statistical strategy used to analyze all patients as part of a group whether or not they met eligibility criteria, received full treatment, or completed the trial.

Hemkens and Waltering were unable to reproduce the number of patients ($n = 120$) for each group from Fig. 1. The completers analysis set consisted of subjects who signed an informed consent form, were randomized, and completed the study as described. These criteria were written in the SAS code, so the results listed in the article represented all subjects who fit the designation of completers. In the NPWT and AMWT groups, 240 subjects (120 per group) met the definition for completers.

Hemkens and Waltering are correct in stating that no data were reported for 3- and 9-month follow-up phases. Due to space constraints, only data from the active treatment phase were analyzed, so recidivism was not reported.

The randomized controlled trial primary end point was to determine the effect of NPWT on incidence of complete ulcer closure. However, the results discussed in the article demonstrate that NPWT is effective for treating diabetic foot ulcers and has a positive effect on outcomes such as secondary amputations. As for occurrence of infections, there was no statistical significance found between specific infection types and treatment type.

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Reference

1. Hemkens LG, Waltering A: Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial: response to Blume et al. (Letter). *Diabetes Care* 31:e76, 2008. DOI: 10.2337/dc08-0890
2. Blume PA, Walters J, Payne W, Ayala J, Lantis J: Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. *Diabetes Care* 31:631–636, 2008